



ROWAN PROCEDURES

A. Protocol Submission

The HUMAN RESEARCH REVIEW APPLICATION is available in hard copy from the Office of Research or on the web at: http://www.rowan.edu/open/provost/research/Integrity_and_compliance/Irb/Irb.cfm. Requests for exemption, expedited review, and full panel review must all be submitted on the aforementioned 11/09 revised form. Protocols submitted on earlier forms will be returned without review, for resubmission on the updated form.

The deadline for submission of the application is two weeks prior to the next meeting of the IRB. IRB meeting dates and submission dates are available at: http://www.rowan.edu/open/provost/research/Integrity_and_compliance/Irb/2009SubmissionSchedule_000.htm

All materials are to be sent to:

The Institutional Review Board for the Protection of Human Subjects in Research
Research Office, Bole Hall 123
201 Mullica Hill Road, Glassboro, NJ 08028.

Questions can be directed to:

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B. Continuing Review

Federal regulations do not allow the IRB to approve a study for more than one year. For multi-year research the principal investigator is responsible for submitting a continuation application one month prior to the expiration of the current IRB approval. Continuing review forms are mailed a few months prior to the expiration date of the current approval period. If the continuation form is not received in a timely manner, the protocol will administratively be made inactive. Continuing review and approval is still necessary if recruitment of subjects stops, but previously enrolled subjects continue to participate in the research, or if the study is in the data analysis phase.

C. Amendments

If a significant change from a previously approved protocol is to be made an amendment must be submitted for review. There is no set form for this procedure. Investigators should reference the original protocol form as a guide to the type of information required when submitting an amendment.

D. Adverse Events

The Institutional Review Board for the Protection of Human Subjects in Research (IRB) has approved the use of a new form to report adverse and/or unexpected events that are experienced by human subjects in research protocols. This is a routine reporting procedure that is required by the federal Office of Human Research Protections (OHRP) for use by investigators in the event that one or more of their subjects experiences an unanticipated event that involves increased risk to themselves or others, while enrolled in a research study. Federal policy [45 CFR 46] includes adverse event reporting as a component of mandatory continuing review of approved protocols, with the stipulation that serious adverse events be reported immediately if they occur. The Adverse/Unexpected Event form may be downloaded from the web at: http://www.rowan.edu/open/provost/research/Integrity_and_compliance/Irb/Irb.cfm or obtained from the Office of Research.

E. Student Research Projects

All student research involving human subjects requires that approval from the IRB has been obtained for their research project and that approval was granted prior to the initiation of the research.

In the case of a student course-related research project assignment, it may be difficult at times to draw the line between that which would require either an IRB or exemption review, and that which is designed simply to provide an experience in research methodology. In an effort to clarify the matter, the IRB has established the following guidelines for determining when institutional review and approval is necessary for projects that are part of an academic course:

1. Student projects that are solely classroom directed exercise are not subject to review by the IRB if the following conditions are met: [i] the research takes place in a Rowan University classroom, departmental, dormitory, or other (Rowan University) campus setting, or in a public setting with generally unlimited access to the public, such as a shopping center, park, or street, [ii] it involves only the learning of research techniques, [iii] it does not put the subjects at more than minimal risk, [iv] the data are recorded anonymously by the students (i.e., with no names, social security numbers, or any other codes that can be linked to a list of names), and [v] the research is not prepared for publication or presentation beyond the classroom.

2. Student projects qualifying under one or more of the six federally allowed exempt categories, but not suited to item 1 above should be submitted to the IRB with a request for exemption. As an example, all of the students' projects might involve interview procedures in which data is collected anonymously (i.e., with no names, social security numbers, or any other codes that can be linked to a list of names) or otherwise qualifying under exemption category 2 of the Federal Regulations. Requests for granting this type of exemption must be received at the IRB office not later than September 12 for the Fall term or February 12 for the Spring term. The request for exemption should be submitted at least a month before the students will begin their projects. For the purposes of this guideline, an exemption request form should be completed by the course instructor, and all of the student projects, qualifying as exempt shall be aggregated as "one classroom project." Exemption requests are considered and acted upon by a subcommittee of the IRB.

3. All non-exempt student research projects that do not qualify under (E1) or (E2) above must be submitted for full IRB review. A faculty member may choose to have the students design and conduct individual projects that do not qualify under an exemption category. All requests for review of non-exempt projects that are to be completed during the Fall semester must be submitted by October submission deadline for consideration at the October IRB meeting. For non-exempt projects to be completed during the Spring semester, the requests for review must be submitted to the IRB by the February submission deadline for review at the February IRB meeting. In the case of a two-semester course, the students should submit their requests for review at least a month before they wish to start their data collection. It shall be the responsibility of faculty members to familiarize themselves with the Rowan regulations for approval of these projects, to review and, if necessary, to assist students in the modification of each project before it is submitted to the IRB office. The IRB is aware that if approval of student projects is not obtained according to the above schedule (October and February deadlines), it may not be possible for the projects to be completed in a timely manner and will provide consultation to the extent that its resources allow.

NOTE: Student research as described in categories 2 and 3 may not meet the definition of research (45 CFR 46), as strictly interpreted, if there is no intent, at the time of submission of the protocol, to disseminate the results (i.e., develop or contribute to general knowledge). Nonetheless, IRB policy is to review these types of student research, which incorporate all of the elements of protocol design utilized by more experienced researchers. In fact, there exists the possibility that the protocol may be so well-designed and orchestrated, and yield such significant results, that general conclusions may be drawn from analysis of the data. The IRB has resolved that the competency level of the researcher should not remove the protocol from the purview of the IRB, in essence due to lack of intent to disseminate results, and therefore requires review of all student research projects that do not meet the criteria of category 1 described above.

Students submitting a protocol must have a faculty sponsor. The faculty sponsor may certify that they are responsible for the student having the accepted training required of researchers at other levels, so that the student is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training and experience to conduct the particular study.

F. Notification

The IRB will notify the applicant of the outcome of the IRB team review within two weeks of the date of the IRB meeting following the submission of the application.